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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/803,570	03/09/2001	William R. Fiehler	S-8165-CON	6856

7590 04/19/2004

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BOSTON, MA 02111

EXAMINER

KIM, SUN U

ART UNIT	PAPER NUMBER
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1723

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/803,570

Applicant(s)

FIEHLER, WILLIAM R.

Examiner

John Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-11 and 14-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30 is/are allowed.
- 6) ☒ Claim(s) 1,3-11 and 14-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. Claims 1, 3-5 and 18-23 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,494,590 (hereinafter referred to as Smith et al.). Smith et al teach a blood collection device comprising a tube (10) defining an inner surface and a closed end and thixotropic gel material (14) selectively deposited radially contiguous on the central inner surface of the tube (10) and displaced a distance relative to the end wherein thixotropic gel is introduced and temporarily fixed at a first position on central inner surface by an inherent dispensing apparatus (see figure; col. 8, line 12 – col. 10, line 23). Smith et al teaches the separation of blood by centrifuging the tube (see col. 10, lines 19-23).

2. Claims 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al as applied to claim 5 above, and further in view of U.S. Patent No. 3,516,385 (Walling). Claims 6-10 essentially differ from the apparatus of Smith et al in reciting a dispensing apparatus having a nozzle with a plurality of openings disposed about a portion of a circumference thereof through which gel is dispensed. Walling teaches that coating materials are coated in the interior of tubular members by a centrifugal distributor with nozzle having a plurality of openings disposed about a portion of a circumference thereof and the number and size of the openings and the speed of a lancer holding the centrifugal distributor will determine the thickness of the coating and inherently the shapes of the coating (see col. 7, line 41 - col. 9, line 50). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to incorporate the known coating apparatus having a nozzle with a plurality of openings in the tube of Smith et al to coat the inner surface of a tube with gel for separating blood components.

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3. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al as applied to claim 4 above, and further in view of U.S. Patent No. 4,257,886 (hereinafter referred to as Kessler). Claim 11 essentially differ from the apparatus of Smith et al in reciting a non-stick coating selectively disposed on the central inner surface. Kessler teaches a blood -collection device comprising a tube (10) with a hydrophobic coating (30) on the inner surface of the tube and thixotropic gel material (28) placed in a bottom inner central surface of the tube (10) with a syringe (see figures 1-3; col. 2, line 46 - col. 6, line 21). Kessler teaches that generally lower 40 to 60 percent of the length of the inner surface of the container will normally need to be coated with hydrophobic material in order to provide an adjacent hydrophobic surface for the barrier material and the heavier portion of the blood (see col. 5, lines 3-11). Hydrophobic coating is a non-stick coating for hydrophilic component of blood. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to incorporate a non-stick coating such as a hydrophobic coating selectively disposed on the central inner surface of the tube of Smith et al to provide an adjacent hydrophobic surface for the barrier material and the heavier portion of the blood as suggested by Kessler.

4. Claims 14-17 and 24-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. Smith et al teach the blood collection device and method as described in above paragraph 3. Claims 14-17 and 24-29 essentially from the method and device of Smith et al in reciting the step of determining first and second limit based on the claimed formula depending on the linear dimension of the blood collection tube and a constant based on at least one factor of the blood collection apparatus. Smith et al teach that a layer of thixotropic gel is at first position of the container and the liquid

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density separation medium (16) is at a second position further away from the open end of the container and the anticoagulant solution is at a position closer to the open end of the container than the layer of thixotropic gel (see col. 6, lines 26-37; col. 8, lines 47-67).

Furthermore, Smith et al teach that a free space adjacent to the open end of the tube positioned above anticoagulant solution (16) is of a sufficient volume to receive a sample of whole blood or a fraction thereof, either alone or in conjunction with an added reagent (see col. 9, lines 22-30). From this, it is apparent that the space occupied by the thixotropic gel is limited by the volume occupied by the liquid density separation medium and anticoagulant solution and sample volume of blood to be received in the tube but sufficient to separate blood phases. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to determine the limits of thixotropic gel based on the linear dimension of the tube and volumes occupied by the liquid density separation medium and anticoagulant solution and sample volume of blood to be received in the tube for providing sufficient thixotropic gel to separate blood phases.

5. Claim 30 is allowed.

6. Applicant's arguments filed 2/17/04 have been fully considered but they are not persuasive. Applicant argues that Smith et al do not disclose, *inter alia*, a gel being selectively deposited and radially contiguous on the inner surface of a tube and displaced a predetermined distance, within predetermined limits, relative to the end. Applicant further argues that the predetermined distance being based on at least one dimension of the blood collection tube and a volume of blood sample being collected. However, Smith et al teach that thixotropic gel material (14) is selectively deposited radially contiguous

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on the central inner surface of the tube (10) and displaced a distance relative to the end wherein thixotropic gel is introduced and temporarily fixed at a first position on central inner surface by an inherent dispensing apparatus (see figure; col. 8, line 12 – col. 10, line 23). Regarding the argument that the predetermined distance being based on at least one dimension of the blood collection tube and a volume of blood sample being collected, the amount of thixotropic gel material is inherently the amount necessary to process the volume of blood occupying the free space (20) and such space and the amount inherently depends on the dimension of the tube.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (571) 272-1142.

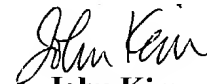
The examiner can normally be reached on weekdays from 7:00 AM - 3:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (571) 272-1151. The fax phone number for official response is (703) 872-9306.

When sending a draft amendment by fax, please mark the paper as "DRAFT"; otherwise, mark the paper "OFFICIAL". This will expedite the processing of the paper.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.



John Kim

**Primary Examiner
Art Unit 1723**

J. Kim
April 16, 2004